

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	10/088,884	FRANK, R. KEITH
	Examiner	Art Unit
	Brian S Kwon	1614

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Amendment filed 1/24/2004 and Telephonic Interview on 5/28/04.
2.  The allowed claim(s) is/are 1 and 7.
3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review ( PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 05102004.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Elisabeth T. Jozwiak on May 28, 2004.

The application has been amended as follows:

(Amended). 1. A method for ~~preventing~~ or minimizing loss of bone mineral in mammals which method comprises administering to a mammal an amount of an aminoalkylenephosphonate or a pharmaceutically acceptable salt thereof which is effective to ~~prevent~~ or minimize loss of bone mineral density, wherein the aminoalkylenephosphonate is selected from the group consisting of 3,6,9,15-tetraazabicyclo[9.3.1]tetradeca-1(15),11,13-triene-3,6,9-trimethylenephosphonic acid (PCTMP), N,N'-bis(methylenephosphonic acid)-2,11-diaza[3.3](2,6)pyridinophane (BP2MP), and N,N'-bis(methylenephosphonic acid)-2-(aminomethyl)pyridine (AMPDMP).

(Amended) <sup>7</sup> A method for ~~preventing~~ or minimizing loss of bone mineral in mammals which method comprises administering to a mammal a pharmaceutical formulation consisting essentially of an amount of aminoalkylenephosphonate or a pharmaceutically acceptable salt which is effective to ~~prevent~~ or minimize loss of bone mineral density, wherein said aminoalkylenephosphonate is 1,4,7,10-tetraazacyclododecane-1,4,7,10-tetramethylenephosphonic

acid (DOTMP), with the proviso that the DOTMP is not complexed with Gallium III, Tin IV, Indium III, Samarium III or Cerium III.

### Reasons for Allowance

The following is an examiner's statement of reasons for allowance: With respective to claim 7, as taught by Jia (lines, 1-14), one having ordinary skill in the art would have known that the metal-ligand complex with DOTMP is required to interfere or block bone resorption or prevent further destruction of the bone. In examiner's opinion, it would not have been obvious to a person of ordinary skill in the art to expect that the administration of DOTMP which is not complexed with the metals would minimize the loss of bone mineral density especially in view of applicant's use of term "consisting essentially of".

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 273-0584. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon  
Patent Examiner  
AU 1614



**Viekie Kim**  
**PRIMARY EXAMINER**  
**GROUP 1600**